CLAIMS

1. Pharmaceutical composition comprising particles of metformin and particles of a fibrate, wherein metformin acts as a carrier for fenofibrate, wherein said metformin and fibrate are present in a combined amount of at least 50% by weight, based on the total weight of the composition, and wherein the weight ratio of metformin to fibrate is comprised between 500:90 and 850:35, and with the provision that if the weight ratio of metformin to fibrate is comprised between 500:90 and 500:65, said composition comprises a dispersion aid as a mandatory excipient.

2. Pharmaceutical composition according to claim 1, wherein the weight ratio of metformin to fibrate is comprised between 500:54 and 850:65.

3. Pharmaceutical composition according to claim 1, wherein the weight ratio of metformin to fibrate is comprised between 850:54 and 850:35.

4. Pharmaceutical composition according to any of claims 1 to 3 in which at least about 70% of the fibrate is dissolved within about 15 minutes, at least about 80% of the fibrate is dissolved within about 30 minutes, at least about 85% of the fibrate is dissolved within about 45 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium containing 0.025 M sodium lauryl sulfate.

5. Pharmaceutical composition according to any of claims 1 to 4, comprising:

- from about 60% to about 98% by weight, preferably from about 70% to about 95% by weight, and most preferably from about 74% to about 90% by weight of fibrate and metformin combined together; and
- from about 2% to about 40% by weight, preferably from about 5% to about 30% by weight, and most preferably from about 10% to about 26% by weight of pharmaceutically acceptable excipients.

6. Pharmaceutical composition according to any of claims 1 to 5, wherein said fibrate is in a crystalline phase, an amorphous phase, a semi-crystalline phase, or a semi-amorphous phase.

7. Pharmaceutical composition according to any of claims 1 to 6, wherein the fibrate is selected from the group consisting of gemfibrozil, fenofibrate, bezafibrate, clofibrate, ciprofibrate, beclofibrate, binifibrate, ciplofibrate, clinofibrate, etofibrate, nicofibrate, pirifibrate, ronifibrate, simfibrate, or theofibrate, a fibric acid derivative or a pharmaceutically acceptable salt or ester of said fibric acid derivative.

8. Pharmaceutical composition according to any of claims 1 to 7, wherein the fibrate is fenofibrate, fenofibric acid or a pharmaceutically acceptable salt or ester of fenofibric acid.

9. Pharmaceutical composition according to any of claims 1 to 8, wherein the fibrate is fenofibrate.

10. Pharmaceutical composition according to any of claims 1 to 9, wherein the fibrate is micronised or co-micronised.

11. Pharmaceutical composition according to any of claims 1 to 10, wherein the fibrate is co-micronized with a surfactant.

12. Pharmaceutical composition according to any of claims 1 to 11, wherein the particles of fibrate have an average size of less than about 20 μm, preferably of less than about 10 μm.

13. Pharmaceutical composition according to any of claims 1 to 12, wherein the fibrate is in the form of nanoparticles having an average size of less than about 2000 nm, preferably of less than about 1500 nm, preferably of less than about 1000 nm, preferably of less than about 500 nm, and preferably of less than about 100 nm.

14. Pharmaceutical composition according to any of claims 1 to 13, wherein metformin is in the form of the free base or one of its pharmaceutically acceptable salts.

15. Pharmaceutical composition according to any of claims 1 to 14, comprising 2000 mg of metformin and 160 mg of fenofibrate; 850 mg of metformin and 80 mg of fenofibrate; 850 mg of metformin and 54 mg of fenofibrate; 500 mg of metformin and 80 mg of fenofibrate; 500 mg of metformine and 54 mg of fenofibrate; or 500 mg of metformin and 40 mg of fenofibrate; 500 mg of metformin and 45 mg of fenofibrate, 500 mg of metformin and 71 mg of fenofibrate, 850 mg of metformin and 71 mg of fenofibrate, 850 mg of metformin and 145 mg of fenofibrate, 1600 mg of metformin and 145 mg of fenofibrate.

16. Pharmaceutical composition according to any of claims 1 to 15, wherein the composition is formulated for oral, pulmonary, rectal, ophthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, or topical administration.

17. Pharmaceutical composition according to any of claims 1 to 16, which is a tablet.

18. Pharmaceutical composition according to any of claims 1 to 16, which is a capsule.

19. Pharmaceutical composition of claim 17, which is in the form of a tablet weighing from about 500 to about 1500 mg.

20. Pharmaceutical composition according to any of claims 1 to 19, further comprising one or more active substances selected from the group consisting of PPARγ activators, HMG CoA reductase inhibitors and antihypertensives.

21. Use of metformin in a pharmaceutical composition comprising metformin and fenofibrate, wherein metformin acts as a carrier for the fibrate,

22. Use of metformin according to claim 21, wherein metformin and fibrate are present in a combined amount greater than or equal to 50% by weight with respect to the overall weight of the composition.

23. A process for preparing a pharmaceutical composition as defined in one of claims 1 to 20, wherein said pharmaceutical composition comprises granulates obtained by the process comprising the steps of:
a) preparing an aqueous dispersion of the fibrate, preferably in the presence of at least one binder and/or surface stabilizer;
b) spraying the resulting dispersion onto a fluidized bed of metformin, whereby granulates are obtained;
c) drying the resulting granulates.

24. A process for preparing a pharmaceutical composition as defined in one of claims 1 to 20, wherein said pharmaceutical composition comprises granulates obtained by the process comprises the steps of:
a) subjecting to high-shear a mixture of metformin and the fibrate, preferably in the presence of at least one binder and/or surface stabilizer;
b) adding water to the high-sheared mixture whereby granulates are obtained;
c) drying the resulting granulates in a fluid bed dryer.

25. A process for preparing a pharmaceutical composition as defined in one of claims 1 to 20, wherein said pharmaceutical composition comprises granulates obtained by the process comprises the steps of:
a) subjecting to high-shear a mixture of metformin and the fibrate, preferably in the presence of at least one binder and/or surface stabilizer;
b) adding water to the high-sheared mixture whereby granulates are obtained;
c) drying the resulting granulates in a one-pot system.